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DEPARTMENT OF HEALTH AND HUMAN SERVICES

C/F #1124494
Facility ID: 201483
Inspection ID: 2014830005

FDA

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

March 2, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Benjamin Peak, CEO
Dickenson County Medical Center
Hospital Drive
P.O. Box 1390
Clintwood, Virginia 24228

Dear Mr. Peak:

Your facility was inspected on February 17, 2000 by a representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

> **Quality control records for the breast phantom were missing for a period of 11 weeks for the [redacted] unit located in your mammography suite.**

This problem is identified as a Level 1 finding because it identifies a failure to comply with significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against conducting further mammography.

The inspector also noted the following Level 3 deficiency:

> **Darkroom fog and film screen contact tests are not being retained for at least one year. The facility's QC checklist documents these tests as having been completed for the previous year, but only the most recent test films have been retained by the facility.**

(Please note that all QC records must be maintained until the next annual inspection to verify compliance or until an individual test has been performed two additional times at the required frequency, whichever is longer.)

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be sent to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: David J. Gallant, Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

for Lee Bowers
Director, Baltimore District